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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,581	04/07/2004	Mark E. Deem	17315-002002	8576

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT PAPER NUMBER

3734

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,581

Applicant(s)

DEEM ET AL.

Examiner

Lindsey Bachman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6-27-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's amendment filed on 18 August 2006.

Information Disclosure Statement

1. The foreign patents and other documents listed on pages 1-4 in the information disclosure statement filed on September 21, 2005 have been considered. The other documents listed were submitted with application 10/635776.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. **Claims 1, 4, 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Oz, et al. (US Patent Number 6,269,819).**

Art Unit: 3734

5. Regarding Claim 1, Oz'819 discloses a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21) having a fastener releasably attached (column 2, lines 47-54). The fastener is deployed to hold the leaflets of the heart valve together and reduce regurgitation (column 2, lines 47-54).

6. Regarding Claim 4, Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

7. Regarding Claim 6 and 8, Oz'819 discloses that the fastener clips will be made out of nitinol, stainless steel or titanium, which are not bioabsorbable materials, so they will be in place permanently (column 5, lines 14-17). Furthermore, since there are only two leaflets in some valves, it is inherent that the fastener will be holding opposed leaflets. Further regarding Claim 8, it is known that chordae are part of the leaflets, therefore, the opposed chordae are linked when the opposed leaflets are attached.

8. Regarding Claim 7 and 9, Oz'819 discloses that clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

9. Regarding Claim 10, Oz'819 discloses advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3734

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 2, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 1, and in further view of Campbell, et al. (US Patent Number 6,143,024).**

13. Regarding Claims 2, 3 and 5, Oz'819 teaches the limitations of Claim 2, 3 and 5. Oz'819 does not teach the use of a ring that shortens the annulus. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Since Oz'819 teaches the deployment of a structure at the annulus to modify the shape of the annulus, it would have been obvious to deploy any device designed to modify the shape of the annulus, such as the ring taught by Campbell'024 because Campbell'024 teaches that a ring is a known device to modify the annulus.

14. **Claims 11-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aklog (US Patent Application 2005/0004665) in view of Macoviak, et al. (US Patent 20040138745).**

Art Unit: 3734

15. Claims 11, 21 and 27: Aklog'665 teaches a method for modifying a heart valve that includes implanting an annuloplasty device (21) at a heart valve to modify the annulus of a valve and reduce regurgitation in the valve (paragraph [0059] and [0035]) in combination with modifying a spatial relationship between two valve leaflets to reduce regurgitation in the heart valve (paragraph [0035] and [0060]). Aklog'665 teaches that it would be desirable to perform this procedure in a minimally invasive manner (paragraph [0024]). Aklog'665 does not explicitly disclose a method of delivering the annuloplasty device with a catheter.

16. Macoviak'745 teaches a method of modifying a heart valve of a patient by advancing a catheter through a patient's vasculature into the heart from a vascular access point having an annuloplasty device (420) coupled thereto (paragraph [0047] and [0063]); implanting the device from the catheter at the heart valve to modify an annulus and reduce regurgitation (paragraph [0047] and [0006]); in combination with implanting an annuloplasty device, modifying a spatial relationship between a first valve leaflet and a second valve leaflet of the valve to reduce regurgitation in the valve (410). Macoviak'745 teaches that this device can be deliver precutaneously because this results in less trauma for the patient and a faster recovery time. It would have been obvious to modify the device taught by Aklog'665 in a way taught by Macoviak'745 so that it can be delivered precutaneously because this results in less trauma on the patient.

17. Claim 12, 13, 14, 15, 16, 26, 32, 33, 34, 35: Aklog'665 teaches that the spatial relationship between the leaflets can be modified by attaching opposed points on the

Art Unit: 3734

leaflets together (paragraph [0063] and [0064]). It is known that chordae and papillary muscles are part of the leaflets, therefore, the opposed chordae and opposed papillary muscles are linked when the opposed leaflets are attached.

18. Claims 17, 19, 23, 25, 29, 31: Aklog'665 teaches that the annulus is tightened/circumferentially shortened when modified by the ring (paragraph [0061]).

19. Claim 18, 24, 30: Aklog'665 teaches that the annulus is deployed on the atrial side of the annulus (paragraph [0081]).

20. Claim 20: Aklog'665 teaches that the annulus is deployed across an interatrial septum of the heart (paragraph [0081]).

21. Claim 28: Aklog'665 teaches that the annuloplasty device is a ring (paragraph [0035]).

Response to Arguments

22. Applicant's arguments filed 18 August 2006 regarding Claims 1-10 have been fully considered but they are not persuasive.

14. Regarding Claim 1, Oz'819 discloses all the limitations of Claim 1: advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21) having a structure releasably attached (column 2, lines 47-54). The fastener is deployed from the catheter (column 2, lines 47-54) to hold the leaflets of the heart valve together (column 2, lines 47-54) and reduce regurgitation (column 1, lines 10-15). The steps of deploying the structure is done in combination with holding the leaflets of the valve together because Oz'819 teaches using a grasper to grasp the leaves of the valve

Art Unit: 3734

together (column 2, lines 33-46), and releasing a clip to hold the leaves together (column 2, lines 47-54). Oz does not fail to show the step of deploying a structure, as described above. Since the rejection for Claim 1 stands, the rejection for dependent Claims 2-10 also stands.

23. Applicant's arguments, see pages 9-10 of Amendment filed 18 August 2006, with respect to the rejection(s) of claim(s) 11-20, and 27-35 under 103(a) as unpatentable over Oz (US Patent 6,269,819) in view of Campbell (US Patent 6,143,024) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Aklog (US Patent Application 2005/0004665) in view of Macoviak, et al. (US Patent 20040138745).

24. Applicant's arguments with respect to claims 21-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER